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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,904	12/10/2004	Jianhua Feng	1-32526A/FMI	4693

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
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EXAMINER	
MACAULEY, SHERIDAN R	
ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,904	FENG ET AL.	
	Examiner	Art Unit	
	Sheridan R. MacAuley	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *10-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-22 are pending.

Election/Restrictions

1. Applicant's election of Group I, claims 1-9, in the reply filed on June 1, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is still deemed proper and is therefore made FINAL.

2. Claims 10-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

3. Claims 1-9 are examined on the merits in this office action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-6 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. In claims 1, 5 and 9, the phrases "at least 20,000 fold increased purity compared with a crude membrane extract of human embryonic kidney (HEK) 293 cells" and "at

least 50,000 fold increased purity compared with a crude membrane extract of human embryonic kidney (HEK) 293 cells" render the claims indefinite. The purity of the enzyme in a crude membrane extract is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For instance, the concentration of an enzyme in a membrane extract would be dependent upon the growth conditions of the HEK 293 cells, the conditions under which the extract was prepared, the storage temperature of the extract, and many other factors.

7. The phrase "which when associated with cellular proteins has a PKB Ser 473 kinase activity and has an apparent molecular weight of 450-650 kDa" also renders claims 1 and 5 indefinite because it is unclear whether applicant is claiming that the composition comprises a protein which has (a) PKB Ser 473 kinase activity and an apparent molecular weight of 450-650 when it is associated with cellular proteins; or (b) PKB Ser 473 kinase activity when associated with cellular proteins, and an apparent molecular weight of 450-650 kDa.

8. Claims 2-4 and 6 are rejected insofar as they depend from claims 1 and 5 and do not provide further clarity.

9. The term "about" in claims 3 and 4 is a relative term that renders the claim indefinite. The term "about" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For example, "about 58 kDa" could include proteins of molecular weight up to 59 kDa, 63 kDa or 70 kDa.

10. It is also unclear which claim applicant intends for claim 9 to depend from, thereby rendering the claim indefinite. The claim is written in dependent form, however applicant has deleted the claim numbers from which the claim previously depended. In the interest of compact prosecution, is has been assumed for examination purposes that applicant intends for the claim to depend from claims 7 or 8.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-9 are rejected under 35 U.S.C. 102(b) as anticipated by Matsuzaki (FEBS Letters, 1996, 305-8) in view of Toker et al. (J. Biol. Chem., 2000, 275:8271-4). Claim 1 recites a composition comprising PKB Ser473 kinase having at least 20,000-fold increased purity compared with a crude membrane extract of human embryonic kidney (HEK) 293 cells, which when associated with cellular proteins has a PKB Ser 473 kinase activity and has an apparent molecular weight of 450-650 kDa. Claim 2 recites the composition of claim 1, having at least 50,000 fold increased purity. Claim 3 recites the composition of claim 1, wherein said composition comprises a protein having a molecular weight of about 48 kDa as estimated by SDS gel electrophoresis. Claim 4 recites the composition of claim 3, wherein said composition comprises a protein having

a molecular weight of about 58 kDa as estimated by SDS gel electrophoresis. Claim 5 recites the purified PKB Ser 473 kinase protein having at least 20,000-fold increased purity compared with a crude membrane extract of HEK 293 cells, which when associated with cellular proteins has a PKB Ser 473 kinase activity and has an apparent molecular weight of 450-650 kDa when fractionated by gel filtration chromatography. Claim 6 recites the purified protein of claim 5, wherein the kinase has at least 50,000 fold increased purity. Claim 7 recites a purified cell extract that has measurable PKB Ser 473 kinase activity in 0.2 micrograms of protein when detected in a kinase assay in which a PKB peptide substrate is phosphorylated with ^{32}P labelled phosphate, wherein the kinase elutes with an apparent molecular weight of 450-650 kDa when fractionated by gel filtration chromatography. Claim 8 recites the purified cell extract of claim 7, wherein the kinase elutes with an apparent molecular weight of about 550 kDa when fractionated by gel filtration chromatography. Claim 9 recites the purified cell extract of claim 7 or 8, wherein the kinase is enriched at least 50,000-fold compared with a crude extract of HEK 293 cells.

13. Matsuzaki teaches a purified RAC-protein kinase (PKB/Akt; abstract). The PBK/Akt (i.e. Akt/Protein Kinase B) has PKB Ser 473 kinase activity when associated with cellular proteins, as evidenced by Toker (abstract). The kinase taught by Matsuzaki has a molecular weight of about 58 kDa (p. 307, fig. 2). Matsuzaki therefore anticipates the composition of the cited claims.

14. The claimed functions, characteristics, and/or traits must be inherent to the reference composition. The discovery of a previously unappreciated property of a prior

art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. Thus the claiming of a new use, functions or unknown property that is inherently present in the prior art does not necessarily make the claim patentable (See MPEP 2112). In this case, the prior art does not disclose how the purity of the claimed composition compares to that of a crude extract of HEK 293 cells, the apparent molecular weight of the protein, particularly when fractionated by gel filtration chromatography when associated with cellular proteins, the activity in 0.2 micrograms of protein, or the presence of an additional protein of the claimed molecular weight. The burden is thus is shifted to the applicant to provide evidence establishing an unobvious difference between the claimed composition and the prior art composition.

15. Therefore, Matsuzaki, in view of Toker, anticipates all of the limitations of the cited claims.

Claim Rejections - 35 USC § 102/103

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 1-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dedhar (US 6,338,958). Claim 1 recites a composition comprising PKB Ser473 kinase having at least 20,000-fold increased purity compared with a crude membrane extract of human embryonic kidney (HEK) 293 cells, which when associated with cellular proteins has a PKB Ser 473 kinase activity and has an apparent molecular weight of 450-650 kDa. Claim 2 recites the composition of claim 1, having at least 50,000 fold increased purity. Claim 3 recites the composition of claim 1, wherein said composition comprises a protein having a

molecular weight of about 48 kDa as estimated by SDS gel electrophoresis. Claim 4 recites the composition of claim 3, wherein said composition comprises a protein having a molecular weight of about 58 kDa as estimated by SDS gel electrophoresis. Claim 5 recites the purified PKB Ser 473 kinase protein having at least 20,000-fold increased purity compared with a crude membrane extract of HEK 293 cells, which when associated with cellular proteins has a PKB Ser 473 kinase activity and has an apparent molecular weight of 450-650 kDa when fractionated by gel filtration chromatography. Claim 6 recites the purified protein of claim 5, wherein the kinase has at least 50,000 fold increased purity. Claim 7 recites a purified cell extract that has measurable PKB Ser 473 kinase activity in 0.2 micrograms of protein when detected in a kinase assay in which a PKB peptide substrate is phosphorylated with ^{32}P labelled phosphate, wherein the kinase elutes with an apparent molecular weight of 450-650 kDa when fractionated by gel filtration chromatography. Claim 8 recites the purified cell extract of claim 7, wherein the kinase elutes with an apparent molecular weight of about 550 kDa when fractionated by gel filtration chromatography. Claim 9 recites the purified cell extract of claim 7 or 8, wherein the kinase is enriched at least 50,000-fold compared with a crude extract of HEK 293 cells.

20. Dedhar teaches a composition comprising a purified integrin-linked kinase (ILK) which has PKP Ser 473 kinase activity when associated with cellular proteins (col. 21-22, example 2, col. 10, ones 43-54). Dedhar teaches that the purified ILK has a molecular weight of 59 kDa, and that the composition also contained a 32 kDa and a 70 kDa protein (col. 21, line 65-col. 22, line 5). The composition of Dedhar had kinase

activity in 0.2 micrograms of protein when detected in a kinase activity assay in which the peptides were labeled with ^{32}P. Dedhar therefore anticipates the invention of cited claims.

21. The claimed functions, characteristics, and/or traits must be inherent to the reference composition. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. Thus the claiming of a new use, functions or unknown property that is inherently present in the prior art does not necessarily make the claim patentable (See MPEP 2112). In this case, the prior art does not disclose the apparent molecular weight of the protein, specifically when fractionated by gel filtration chromatography, in the composition when associated with cellular proteins, or the purity of the protein in the composition compared to a crude membrane extract of HEK 293 cells. The burden is thus is shifted to the applicant to provide evidence establishing an unobvious difference between the claimed composition and the prior art composition.

22. If Dedhar does not anticipate the claimed invention, the motivation to develop the claimed invention is taught by Dedhar, who teaches that HEK 293 cells may be transfected with constructs comprising ILK (col. 41-42, example 13). Dedhar also teaches that proteins which are expressed in any expression system may be purified from a lysate using any way known in the art, including size exclusion chromatography, resulting in a purified protein which is up to 100% pure (col. 8, line 23- col. 9, line 16). One would therefore have been motivated to purify an ILK expressed in an HEK 293 cell using the methods of instant application, thereby resulting in the claimed

composition. One would have a reasonable expectation of success in arriving at the claimed composition because protein purification is well known in the art, as taught by Dedhar.

23. Therefore, Dedhar anticipates all of the limitations of the cited claims or, alternately, the cited claims are rendered obvious over the teachings of Dedhar.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan R. MacAuley whose telephone number is (571) 270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM
/Ruth A Davis/
Primary Examiner, AU 1651